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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1653	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/630,333	Applicant(s) BURMAN ET AL.	
	Examiner Abdel A. Mohamed	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The Examiner in charge of this application has been changed. However, the Group and/or Art Unit location of your application in the PTO remains the same. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

ACKNOWLEDGMENT OF THE AMENDMENT, REMARKS AND STATUS OF THE CLAIMS

2. The amendment and response filed 4/4/02 are acknowledged, entered and considered. In view of Applicant's request claims 15-20 have been canceled. Thus claims 1-14 are now pending in the application. The objection to the Trademarks has been withdrawn in view of Applicant's amendment filed 4/4/02, however, since there is no amendment to the claims, except for cancellation of non-elected claims 15-20, the previous rejections under 35 U.S.C. 112, first paragraph and 35 U.S.C. 112, second paragraph are maintained essentially for the same reasons of record and the previous Office action is reiterated.

CLAIMS REJECTION-35 U.S.C. 112 1st PARAGRAPH.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the synthesis/preparation of peptide composition comprising a peptide of the general formula I and peptides of SEQ ID NOS:3-12 and using the above peptides at different concentrations individually *in vitro* to determine the cytotoxicity effect or activity of the peptides in various human cell lines, does not reasonably provide enablement for a therapeutically effective pharmaceutical composition containing individual peptides for treatment of cancer in mammals including humans and to a method of administering a therapeutic compound thereof as recited in claims 13-14. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims; e.g., claim 13 is directed to "*in vivo*" "treatment" of any kind of cancer by administering "an effective amount" of the peptide of claim 1; and claim 14 to a method of administering a chemotherapeutic compound of peptide of claim 11, and as to the rest of the claims, they are directed to pharmaceutical compositions comprising the peptide composition claimed in claim 1 and the various sequences of claims 2-11.

The instant specification on page 8, lines 1-27 states that the present invention envisages methods and treatment of cancer using the polypeptides of the present invention, pharmaceutical compositions comprising such polypeptides and process for their preparation. However, except for synthesis of the polypeptides claimed which is disclosed in Examples 1-11 and Examples 12-14 which show the biological activities of the peptides *in vitro* by using cytotoxicity assays such as MTT in human tumor cell lines. The above disclosure and the mere recitation of protocols on

page 8 would not entitle Applicant to a method of treatment of cancer in mammal in general by administering an effective amount of the polypeptides claimed because the scope of the instantly claimed invention are very broad and speculative in that there is no working example or data or evidence which shows that the claimed peptides individually are useful as a pharmaceutical composition by administering as an active ingredient a therapeutically effective amount of the peptide to treat cancer in mammals including humans in the manner claimed in the instant invention. There is no evidence in the instant specification to use or administer the pharmaceutical formulation in therapeutically effective composition as claimed. There is no dosage amount for pharmaceutical composition disclosed, except for the various *in vitro* assays which show the cytotoxicity effect or activity in human tumor cell lines with different concentrations of peptides and analogs as disclosed in Examples 12-14 and the various Tables showing cytotoxicity percentages in the instant specification. Thus, there are no sufficient data or evidence to substantiate such protocols of using a therapeutically effective pharmaceutical composition for treating cancer in general in the manner claimed. Hence, the only support for the claimed therapeutically effective pharmaceutical composition and method of treatment of cancer in mammals by administering a therapeutically effective dose of the pharmaceutical composition thereof in the specification is Applicant's supposition of the invention as recited in the protocols. Furthermore, Applicant's claims are directed to a very large number of compounds by using specific therapeutically effective amount of pharmaceutical composition, and there are no objective factual evidence in the specification showing that treatment has occurred using the

specific therapeutically effective amount of pharmaceutical composition claimed. Thus, it is the Examiner's position that one can not administer specific effective amount of a pharmaceutical composition in all situations without appropriate testing which would require the exercise of undue experimentation, as for example, treating cancer in general in mammals.

Therefore, in view of the above, it would include those that have not been shown or taught to be useful or enabled by the disclosed method of making and using the invention. Moreover, undue experimentation is necessary to determine if and under what conditions, the claimed invention as broadly claimed is enabled, since a vast range of pharmaceutical composition in all kinds of possible compounds are contemplated and are encompassed as well as wide range of situations. The results desired appear to be highly dependent on all variables, the relationship of which are not present in the specification. Hence, one of ordinary skill in the art would not be able to identify all the pharmaceutical preparations with the various peptides either alone or in combination having all kinds of concentrations intended to be effective for the claimed purpose as encompassed in the claims would be effective and under what conditions.

Further, the first paragraph of 35 U.S.C. 112 requires, inter alia, that a patent specification provide sufficient guidance to enable a person skilled in the art to make and use the claimed invention without undue experimentation. In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991). While patent Applicants are not directed to disclose every species that falls within a generic claim, id. At 496, 20 USPQ2d at 1445, it is well settled that "the scope of the claims must bear a reasonable correlation to the scope of the enablement provided by the

specification". In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Where practice of the full scope of the claims would require experimentation; factors to be considered in determining whether a disclosure would require undue experimentation ..... include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Therefore, applying the Wands factors to the facts of this case, one of skill in the art would find that undue amount of experimentation would be required to practice the full scope of the extremely broad claims fro the reasons given above. Thus, in view of the quantity of experimentation necessary, the lack of adequate guidance or working examples or data. and the breadth of the claims, the claims are not commensurate in scope with the enabling disclosure. Accordingly, filing of evidence commensurate with the scope of the claims or amendment of the claims to what is supported by the enabling disclosure is suggested.

CLAIMS REJECTION-35 U.S.C. § 112 2nd PARAGRAPH

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in failing to recite as to the function or activity or use of the peptide pf the formula referred in claim 1 (i.e., it is not clear what the peptide recited in claim 1 is supposed to do).

Claims 13 and 14 are indefinite in the recitation "....administration of an effective amount...." and ".....administering a chemotherapeutic.....", respectively because it is not clear what is meant by the terms "effective amount" and "chemotherapeutic" since no amount of peptide or chemotherapeutic compound is claimed or disclosed, and as such, the metes and bounds of the claims cannot be determined.

ARGUMENTS ARE NOT PERSUASIVE

5. **CLAIMS REJECTION-35 U.S.C. 112[1st] PARAGRAPH**

The rejection of claims 1-14 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the synthesis/preparation of peptide composition comprising a peptide of the general formula I and peptides of SEQ ID NOS:3-12 and using the above peptides at different concentrations individually *in vitro* to determine the cytotoxicity effect or activity of the peptides in various human cell lines, does not reasonably provide enablement for a therapeutically effective pharmaceutical composition containing individual

peptides for treatment of cancer in mammals including humans and to a method of administering a therapeutic compound thereof as recited in claims 13-14. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims; e.g., claim 13 is directed to "*in vivo*" "treatment" of any kind of cancer by administering "an effective amount" of the peptide of claim 1; and claim 14 to a method of administering a chemotherapeutic compound of peptide of claim 11, and as to the rest of the claims, they are directed to pharmaceutical compositions comprising the peptide composition claimed in claim 1 and the various sequences of claims 2-11.

Applicant's arguments filed 4/4/02 have been fully considered but they are not persuasive. Applicant has argued that 1) the compounds (i.e., SEQ ID NOS: 3-12) have been tested on sufficiently large number of cancers (i.e., cancer cells) *in vitro*, which include cell lines of different cancer cells such as adenocarcinoma, squamous cell carcinoma, cancer of the central nervous system and leukemia. Since all the tested compounds show cytotoxic activity on the cell lines tested, it is reasonable to believe that these compounds would show anticancer activity on other adenocarcinomas (such as cancers of the gastrointestinal tract, prostate, renal, hepatic, bladder, oesophagus, etc), squamous cell cancers (head and neck, skin, non small cell lung cancer, etc), cancers of the central nervous system (neuroblastomas, astrocytomas, medulloblastomas, etc) and other leukemia; 2) the legal standard imposed by 35 U.S.C. § 112, first paragraph has been met because Applicant through detailed objective guidance and examples by incorporating various reference and patents teaches the manner and process of

making and using the invention in terms commensurate in scope with the claims; 3) consequently, Applicant has provided sufficient information in the disclosure and from the prior art to teach a correlation between the *in vitro* tests and the *in vivo* tests; 4) no *in vivo* working examples are required in a specification in order for it to meet the requirements of § 112, first paragraph for administering the compounds as taught; 5) and concludes by stating that Applicant has established that the peptides of this invention are effective against a wide range of types of cancer and that efficacy in *in vitro* models is predictive of efficacy in *in vivo* systems, and as such, the present application contains sufficient disclosure within the meaning of 35 U.S.C. 112, first paragraph, to teach those skilled in the art how to make and use the claimed invention without any undue experimentation, and thus, there is insufficient evidence to support the rejection as set forth in the Official Action, that one having ordinary skill in the art could practice the claimed invention without undue experimentation, and that the requirements of the first paragraph of 35 U.S.C. § 112 have been met is not persuasive.

Contrary to Applicant's arguments, it the Examiner's position that there is no evidence in the instant specification to use or administer the peptidic formulation in therapeutically effective composition as claimed. There is no dosage amount for pharmaceutical composition disclosed, except for improperly incorporating references. Thus, there are no sufficient data or evidence to substantiate the protocols recited in the instant specification for use in the manner claimed. Hence, the only support for the claimed pharmaceutical formulation, method of making the formulation and method of administering thereof in the specification is Applicant's supposition

of the invention as recited in the protocols. Furthermore, Applicant's claims are directed to a very large number of compounds comprising the peptide compositions claimed in claim 1 and the various sequences of claims 2-11 for therapeutic treatment of all kinds of neoplastic/cancer diseases, and there are no objective factual evidence in the specification showing that treatment has occurred using the specific peptidic formulation claimed. Thus, it is the Examiner's position that one can not employ or use or administer specific peptidic formulation in all situations without appropriate testing. Therefore, in view of the above, it would include those that have not been shown or taught to be useful or enabled by the disclosed method of making and using the invention. Moreover, undue experimentation is necessary to determine if and under what conditions, the claimed invention as broadly claimed is enabled, since a vast range of peptidic formulation in all kinds of possible therapeutic treatment of cancers are contemplated and are encompassed as well as wide range of situations. The results desired appear to be highly dependent on all variables, the relationship of which are not clearly disclosed. Hence, one of ordinary skill in the art would not be able to identify all the peptidic preparations with wide range of dosages intended to be effective for the claimed purpose as encompassed in the claims would be effective and under what conditions. Thus, it is the Examiner's position that one can not administer specific dosage unit of a pharmaceutical formulation in all situations without appropriate testing which would require the exercise of undue experimentation, as for example, using the formulation for *in vivo* treatment of any kind of cancer by administering "an effective amount" of the peptide of claim 1 and the various sequences of claims 2-11.

Further, Applicant acknowledges that the application does not contain any *in vivo* examples, but asserts that *in vivo* examples are not necessary, since the specification teaches those skilled in the art how to use the claimed invention. Based on the *in vitro* data, one skilled in the art with sufficient in formations from *in vitro* examples coupled with the teachings in the application and the skilled person's understanding of the art to practice the claimed invention would not need to have any *in vivo* examples in the specification because the efficacy in *in vitro* models is predictive of efficacy in *in vivo* systems (See page 6 of Applicant's remarks filed 4/4/02).

Contrary to Applicant's assertion, the mere recitation of the protocols and the showing of *in vitro* activity of the peptidic formulation claimed would not entitle Applicant to methods of treating all kinds of cancers because Applicant has not shown that there is a correlation between *in vitro* data and *in vivo* use of the claimed invention. Thus, the burden is on the Applicant to show the correlation exists. Further, *in vitro* results are not basis for extrapolation in use *in vivo* situations. Although, *in vitro* assays are useful in screening for potentially useful therapeutic agents; one can not simply extrapolate the data to an *in vivo* system. The success of the claimed method is dependent on an adequate concentration of drug reaching the desired site *in vivo*. There are many pharmacokinetics properties of drugs such as half-life, deactivation by the liver, binding to plasma proteins, rapid excretion, etc., that can not be ascertained by *in vitro* experiments. Hence, without supporting data based on tests conducted with the formulations claimed herein for the method of treatment of all kinds of cancers in patients contemplated by

Applicant that establish otherwise, this invention is not commensurate with the scope as claimed, or some correlative evidence that establishes the *nexus* between the protocols and *in vivo* data of the specification and successful treatment of various cancers in patients, and as such, the disclosure fails to comply with 35 U.S.C. 112, first paragraph requirements.

Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims; e.g., claim 13 is directed to "*in vivo*" "treatment" of any kind of cancer by administering "an effective amount" of the peptide of claim 1; and claim 14 to a method of administering a chemotherapeutic compound of peptide of claim 11, and as to the rest of the claims, they are directed to pharmaceutical compositions comprising the peptide composition claimed in claim 1 and the various sequences of claims 2-11.

With respect to Applicant's allegation that Applicant has established that peptides of this invention are effective against a wide range of types of cancer and that efficacy in *vitro* models is predictive of efficacy in *in vivo* systems is unpersuasive. Contrary to Applicant's allegation, the state of prior art clearly teach that it is not possible to duplicate or predict the *in vitro* efficacy to *in vivo* situation of animal models infected with tumors (i.e., *in vitro* system can not be duplicated or mimicked in the actual pathophysiological conditions existing in animals infected with tumors). For support, See for example the following references (Jaine, Sci. Amer. Vol. 271, pp. 58-65, July 1994), the reference teaches the mechanisms of barriers to drug delivery in solid tumors in which the resistance to penetration by drugs can play a significant role in undermining

therapy. The reference shows that such resistance can explain why drugs that eradicate tumor cells *in vitro* often fails to eliminate malignancies *in vivo* (See e.g., pages 58-65 and particularly, page 58). Further, Curti (Critical Reviews in Oncology/Hematology, Vol. 14, pp. 14-29, 1993) discloses the physical barriers to drug delivery in tumors in which the chaotic nature of tumor blood vessels and blood flow, the varied composition of the tumor interstitium and disturbed convection and diffusion in the interstitial space of tumors all create significant potential physical barriers to the delivery of therapeutic agents to neoplastic cell *in vivo*. The reference shows that it is not possible to duplicate or predict the hostile micro environment by any *in vitro* system and animal models do not mimic the actual pathophysiological conditions existing in animals infected with tumors. The reference concludes by stating that it is yet not known in cancer therapy if the drug reaches its target and stays there (See e.g., pages 30 and 36). Furthermore, Ross et al. (Immunology Today, Vol. 11, no. 6, 1990) describe the problems associated in the investigational study and clinical use of cancer immunotherapy (See the entire document).

Moreover, Siemen (in Rodent Tumor Models in Experimental Cancer Therapy, edited by Robert F. Kallman, published by Pergamon Press, 1987, pp. 12-15) states on page 12, second paragraph that no perfect animal model for human cancer exists and indicates that satisfactory and unsatisfactory tumor models and factors influencing the selection of a tumor model for experimental evaluation. The reference clearly discusses the advantages and disadvantages of various tumor models such as spontaneous animal tumors, early-generation transplanted tumors, established transplanted tumor lines (these may be slowly or rapidly growing) and human tumor

xenograft, and concludes that there is no universal model for cancer therapy. Similarly, Trott (in Rodent Tumor Models in Experimental Cancer Therapy, edited by Robert F. Kallman, published by Pergamon Press, 1987, pp. 6-11) discusses the rodent tumor models in experimental cancer therapy in which he identifies the differences between mouse and human tumors that clearly shows that rodent tumors could not be models for human tumors for the following reasons: (1) that tumors in humans grow much more slowly than the rodent tumors; (2) that tumors in humans are not transplanted, whereas most experimental tumors are and (3) that there are differences between autochthonous and transplanted tumors due to anatomical and physiological patterns of tissue interrelationships and vasculature (See e.g., pages 6-11). Hence, both references clearly shows the differences between rodent and human tumors and the reasons why one of ordinary skill in the art could not accept rodent tumors as models for human tumors, let alone *in vitro* data.

Therefore, the state of the art clearly demonstrates the predictability or unpredictability by showing that treatment of cancer including solid tumor, is an area of clinical medicine that remains fraught with complications and often presents an array of suboptimal treatment because a major problem in treating cancer is that most or all of the known therapies have serious adverse or undesired side effects. Thus, considering the nature of the treatment of cancer or tumor growth generally in mammals and particularly solid tumors in humans and the limited success achieved; one skilled in the art would not accept the instantly claimed invention as obviously valid and correct without demonstration of evidence or data.

Therefore, in view of the above and in view of the contemporary knowledge in the art related to neoplastic/cancer diseases in general that all attempts to treat these diseases particularly in humans have been unsuccessful and there is no practical therapeutic treatment for neoplastic/cancer diseases as of to date. Hence, one of skill in the art would not accept the characterization of any and all therapeutic treatment protocols without *in vivo* working example(s) or data or evidence as believable on their face. Further, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims; e.g., claim 13 is directed to "*in vivo*" "treatment" of any kind of cancer by administering "an effective amount" of the peptide of claim 1; and claim 14 to a method of administering a chemotherapeutic compound of peptide of claim 11, and as to the rest of the claims, they are directed to pharmaceutical compositions comprising the peptide composition claimed in claim 1 and the various sequences of claims 2-11.

The Examiner is unable to determine the enablement of the invention as claimed without appropriate *in vivo* working examples. The only support for the claimed invention in the specification is Applicant's supposition of the invention in a form of incorporating patents, general discussion and certain *in vitro* data to support therapeutic utility and protocols. Secondly, the Examiner has clearly shown in the previous Office Action of Paper No. 10 (mailed 12/26/01) and as discussed above that without guidance through working example(s), one of ordinary skill in the art would not predict from *in vitro* data, and the incorporation of various patents,

background discussion and/or information and protocols to employ or administer the pharmaceutical formulation in therapeutically effective composition in the manner claimed. Thus, the specification does not enable any person skilled in the art to which it pertains, or which it is most nearly connected, to use the invention commensurate in scope with the claims. In the express absence of one or more examples, evidence and sufficient guidance, the skilled artisan would be faced with undue experimentation for practicing the invention. Thirdly, it is not understood from Applicant's response how the instant invention, which Applicant considers as novel and inventive, be exemplified without *in vivo* working example(s) or data or evidence. The law requires that a disclosure in an application shall inform those skilled in the art how to use Applicant's alleged discovery, not how to find out how to use it for themselves. See *In re Gardner et al.*, 166 USPQ 138 (CCPA 1970). Therefore, undue experimentation is necessary to determine if and under what conditions, the claimed invention as broadly claimed is enabled. Hence, it is viewed that the specification does not enable the invention as claimed in claims 1-14, as it does not teach how to use the invention to achieve the function of the claims for the reasons discussed above.

Thus, applying the Wands factors to the facts of this case, one of skill in the art would find that undue amount of experimentation would be required to practice the full scope of the extremely broad claims fro the reasons given above. Hence, in view of the quantity of experimentation necessary, the lack of adequate guidance or *in vivo* working examples or data, and the breadth of the claims, the claims are not commensurate in scope with the enabling

disclosure. Accordingly, filing of evidence commensurate with the scope of the claims or amendment of the claims to what is supported by the enabling disclosure is again suggested.

CLAIMS REJECTION-35 U.S.C. § 112 2nd PARAGRAPH

6. The rejection of claims 1-14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to the rejection under 35 U.S.C. 112, second paragraph; it the Examiner's position that independent claim 1 and claims dependent thereof are indefinite and confusing because the claims do not recite functions, and as such, it is unclear as to the function and use of the peptidic compounds and/or formulations recited in the claims. Although, claims 13-14, are drafted as method claims, however, the claims are indefinite and vague because it is not clear as to what kind of cancer diseases the therapeutically effective amount of the peptide and/or chemotherapeutic compound is administered? since no amount pf peptide or chemotherapeutic compound is claimed or disclosed. Also, it is not clear as to the amount of dosage and mode of administration? Applicant has argued that the present method claims are not indefinite and that those skilled in the art would be able to determine the metes and bounds of the present claims. The claims recite administering the peptidic formulation in therapeutically effective amount for the therapeutic treatment of the cancer disease and the dosage amount of the peptidic compounds is clearly recited in the specification. This argument is not found persuasive for the reasons

discussed above and because claims must be analyzed to determine their metes and bounds so that it is clear from claim language what subject matter the claim encompass. See *In re Hammack,* 166 USPQ 204 (CCPA 1970); *In re Moore,* 169 USPQ 236 (CCPA 1971). Also, the definiteness of the claims is important to allow others who wish to enter the market place to ascertain the boundaries of protection that are provided by the claims. See *Ex parte Kristensen,* 10 USPQ 2d. 1701, 1703 (PTO Bd. Pat. App. & Inter. 1989). Thus, in order to obviate the above rejection, it is suggested that Applicant amend the claims to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

ACTION IS FINAL

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CONCLUSION AND FUTURE CORRESPONDENCE

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 5:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Mohamed/AAM

June 26, 2002